CY 2016 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of December 31, 2016

This report reflects the data shown as it is identified in the database.

Selection Criteria:
User Response: Start Date: 1/1/2016 End Date: 12/31/2016
Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 208261	ZEPATIER	GRAZOPREVIR AND ELBASVIR	MERCK SHARP AND DOHME CORP	P	1/28/2016	FOR TREATMENT OF CHRONIC HEPATITIS C VIRUS (HCV) GENOTYPES 1 OR 4 INFECTION IN ADULTS
NDA 205836	BRIVIACT	BRIVARACETAM	UCB INC	S	2/18/2016	IN THE TREATMENT OF PARTIAL ONSET SEIZURES IN PATIENTS 16 YEARS OF AGE AND OLDER WITH EPILEPSY
NDA 208114	DEFITELIO	DEFIBROTIDE SODIUM	GENTIUM SPA	P,O	3/30/2016	PEDIATRIC PATIENTS WITH HEPATIC VENO-OCCLUSIVE DISEASE (VOD), ALSO KNOWN AS SINUSOIDAL OBSTRUCTION SYNDROME
NDA 208573	VENCLEXTA	VENETOCLAX	ABBVIE INC	P,O	4/11/2016	FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) WITH 17P DELETION, AS DETECTED BY AN FDA APPROVED TEST, WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY
NDA 207318	NUPLAZID	PIMAVANSERIN	ACADIA PHARMACEUTICALS INC	P	4/29/2016	FOR THE TREATMENT OF HALLUCINATIONS AND DELUSIONS ASSOCIATED WITH PARKINSON'S DISEASE PSYCHOSIS
NDA 207999	OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMACEUTICALS INC	P,O	5/27/2016	FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) IN ADULTS WITH AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN ADULTS UNABLE TO TOLERATE UDCA
NDA 208054	AXUMIN	FLUCICLOVINE F18	BLUE EARTH DIAGNOSTICS LTD	P	5/27/2016	FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING IN MEN WITH SUSPECTED PROSTATE CANCER RECURRENCE BASED ON ELEVATED BLOOD PROSTATE SPECIFIC ANTIGEN (PSA) LEVELS FOLLOWING PRIOR TREATMENT
NDA 208547	NETSPOT	KIT FOR THE PREPARATION OF GALLIUM GA 68 DOTATATE INJECTION	ADVANCED ACCELERATOR APPLICATIONS USA INC	P,O	6/1/2016	THIS PROVIDES FOR THE USE AFTER RADIOLABELING WITH GA 68, WITH POSITRON EMISSION TOMOGRAPHY (PET) FOR LOCALIZATION OF SOMATOSTATIN RECEPTOR POSITIVE NEUROENDOCRINE TUMORS (NETS) IN ADULT AND PEDIATRIC PATIENTS

NDA 208341	EPCLUSA	SOFOSBUVIR AND VELPATASVIR	GILEAD SCIENCES INC	P	6/28/2016	FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC HEPATITIS C VIRUS (HCV) GENOTYPES 1, 2, 3, 4, 5, OR 6 INFECTION: • WITHOUT CIRRHOSIS OR WITH COMPENSATED CIRRHOSIS; AND • WITH DECOMPENSATED CIRRHOSIS FOR USE IN COMBINATION WITH RIBAVIRIN
NDA 208073	XIIDRA	LIFITEGRAST OPHTHALMIC SOLUTION	SHIRE DEVELOPMENT LLC	P	7/11/2016	FOR THE TREATMENT OF THE SIGNS AND SYMPTOMS OF DRY EYE DISEASE (DED).
NDA 208471	ADLYXIN	LIXISENATIDE	SANOFI-AVENTIS US LLC	S	7/27/2016	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN THE TREATMENT OF ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 206488	EXONDYS 51	ETEPLIRSEN	SAREPTA THERAPEUTICS INC	P,O	9/19/2016	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 51 SKIPPING.
NDA 207695	EUCRISA	CRISABOROLE	ANACOR PHARMACEUTICALS INC	S	12/14/2016	TREATMENT OF MILD TO MODERATE ATOPIC DERMATITIS IN PATIENTS 2 YEARS OF AGE AND OLDER
NDA 209115	RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY INC	P,O	12/19/2016	FOR THE TREATMENT OF PATIENTS WITH DELETERIOUS BRCA MUTATION (GERMLINE AND/OR SOMATIC) ASSOCIATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH TWO OR MORE CHEMOTHERAPIES
NDA 209531	SPINRAZA	NUSINERSEN	BIOGEN IDEC INC	P,O	12/23/2016	FOR THE TREATMENT OF SPINAL MUSCULAR ATROPHY IN PEDIATRIC AND ADULT PATIENTS

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 125509/0.0	ANTHIM	OBILTOXAXIMAB	ELUSYS THERAPEUTICS, INC.	S,O	3/18/2016	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH INHALATIONAL ANTHRAX DUE TO BACILLUS ANTHRACIS IN COMBINATION WITH APPROPRIATE ANTIBACTERIAL DRUGS AND FOR PROPHYLAXIS OF INHALATIONAL ANTHRAX WHEN ALTERNATIVE THERAPIES ARE NOT AVAILABLE OR ARE NOT APPROPRIATE
BLA 125521/0.0	TALTZ	IXEKIZUMAB	ELI LILLY AND COMPANY	S	3/22/2016	FOR THE TREATMENT OF ADULTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY

BLA 761033/0.0	CINQAIR	RESLIZUMAB	TEVA RESPIRATORY, LLC	S	3/23/2016	TO REDUCE EXACERBATIONS, RELIEVE SYMPTOMS, AND IMPROVE LUNGFUNCTION IN PATIENTS 18 YEARS OF AGE AND OLDER WITH ASTHMA AND ELEVATED BLOOD EOSINOPHILS WHO ARE INADEQUATELY CONTROLLED ON INHALED CORTICOSTEROIDS
BLA 761034/0.0	TECENTRIQ	ATEZOLIZUMAB	GENENTECH, INC.	P	5/18/2016	IS INDICATED FOR PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO HAVE DISEASE PROGRESSION DURING OR FOLLOWING PLATINUM-CONTAINING CHEMOTHERAPY OR HAVE DISEASE PROGRESSION WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT TREATMENT WITH PLATINUM-CONTAINING
BLA 761029/0.0	ZINBRYTA	DACLIZUMAB	BIOGEN INC.	S	5/27/2016	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS
BLA 761038/0.0	LARTRUVO	OLARATUMAB	ELI LILLY AND COMPANY	P,O	10/19/2016	FOR THE TREATMENT OF ADULT PATIENTS WITH SOFT TISSUE SARCOMA (STS) WITH A HISTOLOGIC SUBTYPE FOR WHICH AN ANTHRACYCLINE-CONTAINING REGIMEN IS APPROPRIATE AND WHICH IS NOT AMENABLE TO CURATIVE TREATMENT WITH RADIOTHERAPY OR SURGERY
BLA 761046/0.0	ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME CORP.	P	10/21/2016	IS INDICATED TO REDUCE RECURRENCE OF CLOSTRIDIUM DIFFICILE INFECTION (CDI) IN PATIENTS 18 YEARS OF AGE OR OLDER WHO ARE RECEIVING ANTIBACTERIAL DRUG TREATMENT OF CDI AND ARE AT A HIGH RISK FOR CDI RECURRENCE

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - Products that do not qualify for priority review.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).